



DEPARTMENT OF HEALTH AND HUMAN SERVICE

94479d
Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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January 12, 2004

WARNING LETTER NO. 2004-NOL-10

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Errol K. Perera, President
Errol's Cajun Foods, Inc.
6801 Highway 1001
Belle Rose, Louisiana 70341

Dear Mr. Perera:

On September 18, 22, 23, 25 and 29, 2003, we inspected your seafood processing facility, located at 6801 Highway 1001, Belle Rose, Louisiana. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly your various prepared seafood dishes are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulation through links in FDA's Internet home page at <http://www.fda.gov>.

The serious deviations were as follows:

- You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(a) and (c). However, your firm does not have a HACCP plan for shrimp pistolettes to control the food safety hazards of pathogen growth and toxin formation (specifically the pathogen of *Staphylococcus aureus*) and undeclared sulfites.
- You must implement the record keeping systems you listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Batter critical control point to control the bacterial pathogen hazard listed in your HACCP plan for Crab/Crawfish Cakes-Frozen. Also, your firm did not record monitoring observations at the Pack, Code, Label critical control point to control the "allergic reactions

from undeclared sulfiting agents" hazard listed in your HACCP plans for Shrimp Etouffée, Shrimp Gumbo, Seafood Gumbo, Stuffed Shrimp, and Shrimp Stuffed Jalapenos.

- You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However:
 - Your HACCP plans for Stuffed Crabs, Stuffed Shrimp, Crab Stuffed Jalapenos, Shrimp Stuffed Jalapenos, Crab/Crawfish Cakes, Crab Patties and Seafood Stuffing fail to list *Staphylococcus aureus* as a hazard.
 - Your HACCP plans for Crawfish Etouffée, Crawfish Pies, Crab/Crawfish Cakes, Crawfish Pistolette, and all other products containing crawfish fail to list undeclared sulfites as a hazard.
 - Your HACCP plans for Stuffed Shrimp and Seafood Stuffing fail to list *Clostridium botulinum* as a hazard for these vacuum-packaged products. Also, FDA recommends that these products be labeled with adequate storage instructions, such as "Important, keep frozen until used, thaw under refrigeration immediately before use."
- You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, some of your firm's HACCP plans fail to list necessary critical control points needed to control the food safety hazard of pathogen growth and toxin formation due to time/temperature abuse. Specifically:
 - Your HACCP plans for Crab/Crawfish Cakes, Crab Patties, Stuffed Crabs, Crab Stuffed Shrimp, Crab Stuffed Jalapenos, Seafood Gumbo, and Seafood Stuffing and other products containing pasteurized crabmeat do not list the critical control points of receiving and refrigerated storage of pasteurized crabmeat;
 - Your HACCP plan for Crawfish Pies does not list the critical control points of cooling pie filling, [REDACTED] and refrigerated storage of the crawfish and rice pie filling;
 - Your HACCP plans for Crawfish Pistolettes and Oyster Pies/Artichoke Pies do not list the critical control points of [REDACTED] and refrigerated storage; and,
 - Your HACCP plan for Shrimp Stuffed Jalapenos does not list the critical control points of [REDACTED] and [REDACTED];

- You must have a HACCP plan that, at a minimum, lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, several of your HACCP plans fail to list critical limits necessary to control the hazards associated with the listed products.
 - Your HACCP plans for Shrimp and Crawfish Etouffée, Shrimp Gumbo, and Seafood Gumbo list a critical limit, "Proper cool & temp. to prevent pathogen growth after cooking," at the Cool critical control point that is not adequate to control the food safety hazard of pathogen growth due to time/temperature abuse. FDA recommends that you cool your products from 140° F (60° C) to 70° F (21.1° C) or below within 2 hours and to 40° F (4.4° C) or below within another 4 hours.
 - Your HACCP plans for Crawfish Pie, Crawfish Etouffée, Oyster Pie, and Crawfish Pistolettes list a critical limit, "Cook 180 and turn heat off," at the Cook critical control point that is not adequate to control the food safety hazard of "bacterial pathogen survival." Your critical limit should identify the temperature and time parameters for your cook process.

We also note that your retail stuffed shrimp and retail stuffed crab are misbranded within the meaning of Section 403(q)(1) of the Act in that their labels fail to bear nutritional labeling as required by 21 CFR 101.9.

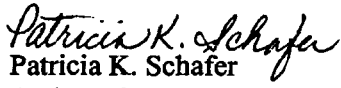
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

We are aware that you made a verbal commitment to correct the deviations during the inspection. However, please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as new and revised HACCP plans, monitoring logs, and corrected product labels or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations, 21 CFR 110. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Hardin at 504-253-4519.

Sincerely,


Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483